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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/727,770	12/04/2000	Zhenya Li	CL000651	5477

25748 7590 09/27/2002

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EXAMINER	
SULLIVAN, DANIEL M	

ART UNIT	PAPER NUMBER
1636	10

DATE MAILED: 09/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/727,770	Applicant(s) LI ET AL.	
	Examiner Daniel Sullivan	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 20 and 21, drawn to an isolated peptide comprising or consisting of the amino acid sequence set forth as SEQ ID NO:2 or variants thereof, classified in class 530, subclass 350.

II. Claims 3 and 12, drawn to an isolated antibody that selectively binds to the isolated peptide of Group I, classified in class 530, subclass 387.1.

III. Claims 4, 5, 8-11, 22 and 23, drawn to an isolated nucleic acid molecule comprising or consisting of a nucleotide sequence encoding the peptide set forth as SEQ ID NO:2, a vector and host cell comprising said isolated nucleic acid molecule, and methods of using, classified in class 435, subclass 69.1.

IV. Claims 6 and 13, drawn to a gene chip comprising a nucleic acid molecule of claim 5 and method of using, classified in class 435, subclass 6.

V. Claim 7, drawn to a transgenic non-human animal comprising a nucleic acid molecule of encoding the sequence set forth as SEQ ID NO:2, classified in class 800, subclass 13.

VI. Claims 14-19, drawn to a method for identifying a modulator or agent that binds to the peptide of Group I comprising contacting said peptide with an agent and determining if the agent has modulated or bound to the peptide, and

pharmaceutical compositions and methods of using said pharmaceutical compositions identified by the method, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I versus II-VI; II versus III-VI; III versus V and VI; IV versus V and VI; and V versus VI are distinct, each from the other. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

The polypeptides of Invention I are related to the antibodies of Invention II by virtue of binding affinity. Although the polypeptides and antibodies are related in that the antibody binds to the polypeptide and can be raised by immunization with the polypeptide, they are distinct inventions because they are physically and functionally distinct chemical entities, and the antibody can be obtained by another and materially different process, such as by purification from a natural source or by immunization with chemically synthesized peptides. Further, the polypeptide may be used for processes other than the production of the antibody, such as a standard in an assay for the presence of the protein.

The nucleic acids of Invention III are related to the protein of Invention I by virtue of encoding the same. The DNA molecule has utility for the recombinant production of the protein in host cells, as recited in claim 10. Although the DNA molecule and protein are related in that the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification

from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The nucleic acids of Invention III are related to the antibodies of Invention II by virtue of the antibodies' binding affinity for a protein encoded by the nucleic acid. Although the nucleic acids and antibodies are related via the polypeptide encoded by the nucleic acids, which binds to the antibodies and can be used to make the antibodies by immunization, they are distinct inventions because they are physically and functionally distinct chemical entities, and the antibody can be obtained by another and materially different process, such as by purification from a natural source or by immunization with chemically synthesized peptides. Further, the nucleic acid may be used for processes other than the production of the protein, such as a nucleic acid hybridization assay.

The peptide of Invention I and nucleic acid of Invention III are related to the transgenic animal of Invention V in that the animal can be produced using the nucleic acid of Invention III and comprises the peptide of Invention I. The animal is distinct from the peptide and nucleic acid, however, because they are physically and functionally distinct and the peptide and nucleic acid can be used for processes other than production of the transgenic animal, such as to raise antibodies, or screen for agents that bind to the protein or nucleic acid.

Likewise, the peptide of Invention I is related to the pharmaceutical composition of Invention VII in that the peptide can be used to identify the pharmaceutical composition. The inventions are distinct, however, because the peptide is physically and functionally distinct from the pharmaceutical composition, and the peptide can be used in materially different processes other than identifying a pharmaceutical, such as to raise an antibody.

The antibody of Invention II is unrelated to the gene chip of Invention IV, the transgenic animal of invention V, the method of Invention VI or the pharmaceutical composition of invention VII. The inventions are not disclosed as capable of use together and clearly have different functions and effects as neither the products nor the method comprise an antibody.

The nucleic acid of Invention III is related to the method of Invention VI as product and method of using. The inventions are distinct, however, because the nucleic acid can be used in a materially different process, such as a nucleic acid hybridization assay, and the method can be practiced without the nucleic acid, such as by measuring binding to a chemically synthesized peptide or expression of an endogenous protein using an antibody.

Similarly, the nucleic acid of Invention III is unrelated to the pharmaceutical composition of Invention VII because, although the nucleic acid can be used in one method of identifying the pharmaceutical composition, the nucleic acid and pharmaceutical composition are structurally and functionally distinct, the nucleic acid can be used in materially different processes such as to in hybridization assays, and the pharmaceutical composition can be identified by materially different processes such as by screening binding to chemically synthesized peptides.

The transgenic animal of Invention V is related to the method of Invention VI and pharmaceutical composition of Invention VII in that the animal or cells from the animal can be used in the method Invention VI. The inventions are distinct, however, because the animal can be used for materially different processes, such as to study phenotype of overexpression of the peptide, and the method can be practiced using a materially different product, such as a transfected cell line or a chemically synthesized peptide.

Inventions III and IV are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed is not solely dependent upon the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed is not solely dependent upon the particulars of the subcombination as claimed because patentability of a gene chip is derived from the aggregate of nucleic acids comprised by the chip and not any single nucleic acid. The subcombination has separate utility such as for expression of the encoded protein.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

dms
September 25, 2002

JAMES KETTER
PRIMARY EXAMINER